| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 11D0260210 | 01/20/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Kaiser Permanente Cumberland Laboratory | 2525 Cumberland Parkway, Atlanta, GA | |

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D0000** | A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 20, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited: |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on calibration document review and staff interview, the lab failed to calibrate |

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| | the POCH-I hematology analyzer every six (6) months as required by the manufacturer. Findings include: 1. Review of calibration data reveals the POCH-I was not calibrated during the year of 2020. 2. Interview with staff #1 (CMS 209 form) on 1 /2/21 at approximately 1:13 PM in the lab, confirmed the lack of 2020 calibrations. |
| **D5517** | MYCOLOGY<br>CFR(s): 493.1263(a)(c)<br><br>The laboratory must check each batch (prepared in-house), lot number (commercially prepared), and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control organism(s). (c) The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of quality control (QC) records for Dermatophyte test media (DTM) and staff interview, the facility failed to perform in-house required quality control on each lot number/shipment of media used to perform fungus cultures. Findings include: 1. Review of February 2019, August 2019, February 2020, and August 2020 QC records reveals the laboratory is not performing in-house QC on DTM media. 2. Interview with staff #1 (CMS 209 form) on January 20, 2021 at 1:00 PM in the lab confirms the laboratory is not performing QC in-house as required. |